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PTO/SB/08A (08-00)

Substitute for form 1449, PTO-10 INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>				<i>Complete if Known</i>	
Sheet	1	of	3	Application Number	09/528,682
				Filing Date	March 20, 2000
				First Named Inventor	PIZZA et al.
				Group Art Unit	1631
				Examiner Name	M. Borin
				Attorney Docket Number	PP000342.0105

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 1 of 3

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U.S. PATENT DOCUMENTS

FOREIGN PATENT DOCUMENTS

**Examiner
Signature**

Date Considered

4/09/05

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Sheet	2	of	3	Attorney Docket Number	PP000342.0105 (2300-0342.10)

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS		
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.
<i>Mir</i>	C1	Burnette, "The Advent of Recombinant Pertussis Vaccines." <i>Biotechnol.</i> 8:1002-1005 (1990)
	C2	Burnette, <i>Vaccine Research & Development</i> Chapter 6, Marcel Dekker Inc., New York, New York (1992)
	C3	Communication to EPO Concerning Replacement Claims for Filing with the EPO in Application No. 99922284.7 (2003)
	C4	de Haan, <i>et al.</i> , "Mutational Analysis of the Role of ADP-Ribosylation Activity in the Adjuvant Properties of the Escherichia Coli Heat-Labile Enterotoxin Towards Intranasally Administered Keyhole Limpet Hemocyanin." <i>Eur. J. Immunol.</i> 28:1243-1250 (1998)
	C5	Del Guidice, <i>et al.</i> , "Genetically Derived Toxoids for use as Vaccines and Adjuvants." <i>Vaccine</i> 17:S44-S52 (1999)
	C6	Dickinson & Clements, "Dissociation of Escherichia coli heat-labile enterotoxin adjuvanticity from ADP-ribosyltransferase activity", <i>Infect. Immun.</i> 63:1617-1623 (1995)
	C7	EPO Communication pursuant to Article 96(2) EPC relating to Application EP No. 94928455.8-2116 (2001)
	C8	"Multicomponent Vaccine Development." <i>NIH Guide</i> Volume 22, Number 28 (1993)
	C9	Green, Bruce, Curriculum Vitae
	C10	Grant et al., "Role of trypsin-like cleavage at arginine 192 in the enzymatic and cytotoxic activities of Escherichia coli heat-labile enterotoxin", <i>Infect. Immun.</i> 62:4270-4278 (1994).
	C11	Hagen, Michael, Curriculum Vitae
	C12	Hagwar, <i>et al.</i> , Effectiveness and Safety of Mutant Escherichia Coli Heat-Labile Enterotoxin (LT H44A) as an Adjuvant for Nasal Influenza Vaccine." <i>Vaccine</i> 19:2071-2079 (2001)
	C13	Hartman, <i>et al.</i> , "Native and Mutant Forms of Cholera Toxin and Heat-Labile Enterotoxin Effectively Enhance Protective Efficacy of Live Attenuated and Heat-Killed Shigella Vaccines." <i>Infect. Immun.</i> 67:5841-5847 (1999)
	C14	Hazama, <i>et al.</i> , "Intranasal Immunization Against Herpes Simplex Virus Infection by using a Recombinant Glycoprotein D Fused with Immunomodulating Proteins, the B Subunit of Escherichia Coli Heat-Labile Enterotoxin and Interleukin-2." <i>Immunology</i> 78:643-649 (1993)
	C15	Hirst, <i>et al.</i> , "Cholera Toxin and Related Enterotoxins as Potent Immune Modulators." <i>J. Appl. Microb. Symp. Suppl.</i> 48:26S-34S (1998)
	C16	Hirst, <i>The Comprehensive Sourcebook of Bacterial Protein Toxins</i> , Chapter 6, Academic Press, pgs. 104-130, (1999)
	C17	Lobet et al., "Effect of site-directed mutagenic alterations on ADP-ribosyltransferase activity of the A subunit of Escherichia coli heat-labile enterotoxin", <i>Infect. Immun.</i> 59:2870-2879 (1991)
	C18	Lycke, <i>et al.</i> , "Strong Adjuvant Properties of Cholera Toxin on Gut Mucosal Immune Responses to Orally Presented Antigens." <i>Immunol.</i> 56:301-308 (1986)
	C19	Lycke, <i>et al.</i> , "The Mechanism of Cholera Toxin Adjuvanticity." <i>Res. Immunol.</i> 198:504-520 (1997)
	C20	Martindale, <i>Royal Pharmaceutical Society of Britain Pharmaceutical Press</i> , London, England, pgs.1277-1304(1993)
	C21	Rappouli, <i>et al.</i> , "Structure and Mucosal Adjuvanticity of Cholera and Escherichia Coli Heat-Labile Enterotoxins." <i>Immunol. Today</i> 20:493-500 (1999)
	C22	Spangler, "Structure and Function of Cholera Toxin and The Related Escherichia Coli Heat-Labile Enterotoxin." <i>Microbiol. Rev.</i> 56:622-647 (1992)
	C23	Streatfield, <i>et al.</i> , "Intermolecular Interactions Between the A and B Subunits of Heat-Labile Enterotoxin from Escherichia Coli Promote Holotoxin Assembly and Stability In Vivo." <i>PNAS USA</i> 89:12140-12144 (1992)
	C24	<i>The Comprehensive Sourcebook of Bacterial Protein Toxins</i> , 2 nd Ed., Academic Press, pgs. 696-697
<i>Mir</i>	C25	Tsuji, <i>et al.</i> , "Relationship Between a Low Toxicity of the Mutant A Subunit of Enterotoxigenic Escherichia Coli Enterotoxin and its Strong Adjuvant Action." <i>Immunology</i> 90:176-182 (1997)

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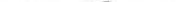
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Sheet	3	of	3	Attorney Docket Number	PP000342. 0105 (2300-0342.10)

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

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